

PATENT APPLICATION

IN THE U.S. PATENT AND TRADEMARK OFFICE

May 17, 2005

Applicants: Alice C. MARTINO et al

For: TABLET FORMULATION

Serial No.: 09/656 364 Group: 1617

Confirmation No.: 3730

Filed: September 6, 2000 Examiner: Sharareh

Atty. Docket No.: Pharmacia Case 6107.N CN2

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

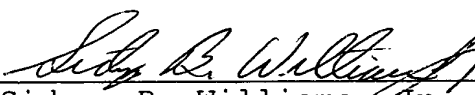
**INFORMATION DISCLOSURE STATEMENT**

Sir:

In compliance with the provisions of Rules 1.97(b)(4) and 1.98, enclosed herewith is Form PTO-1449 and the references cited thereon. These references constitute the art known to the Applicants and are believed to be distinguishable from the claimed invention. Accordingly, further comment at this point in time should not be necessary.

Further consideration is respectfully solicited.

Respectfully submitted,

  
\_\_\_\_\_  
Sidney B. Williams, Jr.

SBW/smd

FLYNN, THIEL, BOUTELL  
& TANIS, P.C.  
2026 Rambling Road  
Kalamazoo, MI 49008-1631  
Phone: (269) 381-1156  
Fax: (269) 381-5465

Dale H. Thiel	Reg. No. 24 323
David G. Boutell	Reg. No. 25 072
Ronald J. Tanis	Reg. No. 22 724
Terryence F. Chapman	Reg. No. 32 549
Mark L. Maki	Reg. No. 36 589
Liane L. Churney	Reg. No. 40 694
Brian R. Tumm	Reg. No. 36 328
Steven R. Thiel	Reg. No. 53 685
Donald J. Wallace	Reg. No. 43 977
Sidney B. Williams, Jr.	Reg. No. 24 949

Encl: Form PTO-1449 and references cited thereon

110.0703

INFORMATION  
DISCLOSURE  
CITATION

Applicant: Alice C. MARTINO et al  
 Ser.No.: 09/656 364 Filed: September 6, 2000  
 Conf. No.: 3730 Atty. Docket No.: Pharmacia Case 6107.N CN2  
 Group: 1617

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Page No.	(Include Author, Title, Date, Pages, Etc.)
	AA	Von. B. ASMUSSEN et al, <b>Drug Release in vitro from Digoxin Formulations with High Bioavailability</b> , <i>Arzneimittelforschung</i> 1980;30(12):2168-72
	AB	A.F. DAVIS et al, <b>Effect of supersaturation on membrane transport: 1. Hydrocortisone acetate</b> , <i>Int.J.Pharm.</i> (1991), 76(1-2), 1-8
	AC	C. DOHERTY et al, <b>The In-vitro pH-Dissolution Dependence and In-vivo Bioavailability of Frusemide-PVP Solid Dispersions</b> , <i>J.Pharm.Pharmacol.</i> 41:73-78(1989).
	AD	K.M. O'DRISCOLL et al, <b>Chlorothiazide-Polyvinylpyrrolidone (PVP) Interactions: Influence on Membrane Permeation (Everted Rat Intestine) and Dissolution</b> , <i>Drug Development and Industrial Pharmacy</i> . 8(4), 547-564(1982).
	AE	H. FUJIOKA et al, <b>Biopharmaceutical Studies on Hydantoin Derivatives. III. Physico-chemical Properties, Dissolution Behavior, and Bioavailability of the Molecular Compound of 1-benzenesulfonyl-5,5-diphenylhydantoin and Anti-Pyrine</b> , <i>J.Pharm.Dyn.</i> 1982 Jul;5(7):475-484.
	AF	M. FUJII et al, <b>Dissolution and Bioavailability of Phenobarbital in Solid Dispersion with Phosphatidylcholine</b> , <i>Chem.Pharm.Bull.</i> , 39(7)1886-1888(1991)
	AG	T. HIGUCHI, <b>Physical Chemical Analysis of Percutaneous Absorption Process from Creams and Ointments</b> , <i>J.Soc.Cosmet.Chem.</i> , 11(1960)85-97.
	AH	W.I. HIGUCHI et al, <b>Drug Membrane Transport Enhancement Using High Energy Drug-Povidone Coprecipitates</b> , <i>Proc.Int.Symp. on Povidone</i> , pp. 71-79, 1993.
	AI	S.L. RAGHAVEN et al, <b>Effect of cellulose polymers on supersaturation and in vitro membrane transport of hydrocortisone acetate</b> , <i>Int.J.Pharm.</i> 193(2000) 231-237
	AJ	N. KONDO et al, <b>Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug</b> , <i>J.Pharm.Sci.</i> , 83 566-570 (1994)
	AK	T. LOFTSSON et al, <b>The effect of polyvinylpyrrolidone and hydroxypropyl methylcellulose on HPβCD complexation of hydrocortisone and its permeability through hairless mouse skin</b> , <i>Europ.J.Pharm.Sci.</i> 2 (1994) 297-301
	AL	T. LOFTSSON et al, <b>The effect of water-soluble polymers on aqueous solubility of drugs</b> , <i>Int.J.Pharm.</i> 127 (1996) 293-296
EXAMINER SIGNATURE		DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

INFORMATION DISCLOSURE CITATION	Applicant: Alice C. MARTINO et al	
	Ser.No.: 09/656 364	Filed: September 6, 2000
	Conf.No.: 3730	Atty. Docket No.: Pharmacia Case 6107.N CN2
	Group: 1617	

## NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.	(Include Author, Title, Date, Pages, Etc.)
	AM	N.A. MEGRAB et al, <b>Oestradiol permeation through human skin and silastic membrane: effects of propylene glycol and supersaturation</b> , J.Control.Rel. 36 (1995) 277-294
	AN	H. SEIKAWA et al, <b>Dissolution Behaviors and Gastrointestinal Absorption of Phenytoin in Phenytoin-Polyvinylpyrrolidone Coprecipitate</b> , Chem.Pharm.Bull., 26, (1978) 3033-3039.
	AO	H. SUZUKI et al, <b>Some Factors Influencing the Dissolution of Solid Dispersions with Nicotinamide and Hydroxypropylmethylcellulose as Combined Carriers</b> , Chem. Pharm. Bull., 46 1015-1020 (1998).
	AP	M.T. LEDWIDGE et al, <b>Effects of surface active characteristics and solid state forms on the pH solubility profiles of drug-salt systems</b> , Int.J.Pharm., 174 (1998) 187-200
	AQ	Abu T.M. SERAJUDDIN et al, <b>Influence of pH on Release of Phenytoin Sodium from Slow-Release Dosage Forms</b> , J.Pharm.Sci. (1993) 82(3), 306-310
	AR	H. SUZUKI et al, <b>Comparison of Nicotinamide, Ethylurea and Polyethylene Glycol as Carriers for Nifedipine Solid Dispersion Systems</b> , Chem.Pharm.Bull., 45 (1997) 1688-1693
	AS	K. YAMAMOTO et al, <b>Dissolution Behavior and Bioavailability of Phenytoin from a Ground Mixture with Microcrystalline Cellulose</b> , J.Pharm.Sci. 1976, 65(10): 1484-1488
	AT	A.P. SIMONELLI et al, <b>Inhibition of Sulfathiazole Crystal Growth by Polyvinylpyrrolidone</b> , J.Pharm.Sci., 59 (1970) 633-638
	AU	A.P. SIMONELLI et al, <b>Dissolution Rates of High Energy Sulfathiazole-Povidone Coprecipitates II: Characterization of Form of Drug Controlling Its Dissolution Rate via Solubility Studies</b> , J.Pharm.Sci., (1976) 65(3), 355-361
	AV	R. WALD et al, <b>Non-Crystallinity, Supersaturation and Relative Bioavailability: Experiences with a Non-Peptidic HIV-Protease Inhibitor</b> , 10 <sup>th</sup> Annual Meeting of American Assoc. of Pharm. Sci., 1995, (24 pages)
EXAMINER SIGNATURE		DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.